K070806

APR 11 2007

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510(k) Summary

Contact: Grant Ramaley, Director of Regulatory Affairs

Date Prepared: January 10, 2007

Trade or Proprietary Name: Model ASC-12 Piezoelectric Scaler

Classification Name: 872.4850 Ultrasonic scaler

510(k) Number:

Device Description: The ASC-12 is an AC mains-powered piezoelectric ultrasonic scaler intended for scaling and endodontic procedures. The device consists of a console, a footswitch and an autoclavable handpiece with interchangeable and autoclavable scaling tips.

The following intended were validated by establishing equivalent scaler tip amplitudes and power settings between a predicate device using their prescribed power settings for the exact same scaler tips to be used with the ASC-12. See tip movement compatibility data.

Features of Substantial Equivalence to the Satelec Suprasson P5 Booster - 510(k) #K961158 and the NSK Varios 350 - 510(k) #K031421

1) **Intended Use**: scaling and endodontic procedures, including:
   Scaling: Interdentium treatment
   Tooth neck and subgingival treatment
   Treatment of large dental calculi
   Treatment of coatings and tobacco stains
   Treatment of periodontal pockets
   Interproximal treatment
   Loosening of crowns and posts
   Endodontics: Pulp Chamber Cleaning
   Canal filling by ultrasonic gutta-percha condensation

2) **Design & Construction**: AC mains-powered piezoelectric ultrasonic scaler consisting of a console, a footswitch and a handpiece with interchangeable scaling tips. Coolant may be supplied by connection to an external water source.
3) **Sterility Assurance**: Handpiece and scaling tips are removable and autoclavable
4) **Performance**:
   a. The vibration frequency is between 27 and 32 kHz
   b. Scaler coolant flow is between 12 ml and 82 ml at the tip
   c. Water pressure rating is between 14.5 to 73 pso (1 to 5 bar)

5) **Electrical Safety Specifications**: Class II equipment with Type BF applied part

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aseptico, Incorporated
C/O Ms. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

APR 11 2007

Re: K070866
Trade/Device Name: ASC-12 Piezoelectric Scaler
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 26, 2007
Received: March 29, 2007

Dear Ms. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070866

Device Name: ASC-12 Piezoelectric Scaler

Indications for Use:

The ASC-12 is an ultrasonic scaler that is intended for the following procedures:

Scaling:
- Interdentium treatment
- Tooth neck and subgingival treatment
- Treatment of large dental calculi
- Treatment of coatings and tobacco stains
- Treatment of periodontal pockets
- Interproximal treatment
- Loosening of crowns and posts

Endodontics:
- Pulp Chamber Cleaning
- Canal filling by ultrasonic gutta-percha condensation

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion Control, Dental Devices

510(k) Number: K070866